

seeing the laws upheld. But Simonian has no standing to seek redress of a non-pecuniary harm to the Government. Accordingly, his complaint should be dismissed, with prejudice, under FED. R. CIV. P. 12(b)(1). Alternatively, the Court may wish to defer resolution of this issue pending the Federal Circuit's decision in the matter of *Stauffer v. Brooks Bros., Inc.*, Appeal Nos. 2009-1428, 2009-1430, 2009-1453, which squarely presents the question whether private citizens like Simonian (who are not market competitors with companies like Merial and can allege no competitive injury) have standing under Article III to prosecute claims for false marking.¹ The Federal Circuit's decision in that case could well dispose of Simonian's complaint entirely.

Second, even setting aside Simonian's lack of standing, his complaint is facially defective. False marking claims must meet the rigorous pleading requirements of FED. R. CIV. P. 9(b) ("Rule 9(b)"), and Simonian's complaint does not come close.

Third, these pleading defects cannot be cured through more artful drafting, for the simple reason that Simonian has no colorable claim to plead against Merial. Given the highly regulated structure surrounding drug approvals, there is no conceivable way that Merial could have intended to deceive a potential competitor from pursuing a competing product by merely including an expired patent number on HEARTGARD. For these reasons, Simonian's complaint fails to state a claim and should be dismissed pursuant to FED. R. CIV. P. 12(b)(6).

II. FACTUAL BACKGROUND

Beginning in 1997, Merial sold HEARTGARD under a license from Merck & Co., Inc. ("Merck"). Merck is the owner of United States Patent No. 4,199,569 ("the '569 Patent"). There is no dispute that the claims of the '569 Patent read upon HEARTGARD. The dispute in this matter arises solely from the fact that the '569 Patent has now expired.

¹ Merial has filed simultaneously its MOTION AND MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO STAY, which further explains the issues pending in the *Stauffer* matter and details why a brief stay of this litigation is warranted.

In his complaint, Simonian alleges that Merial has engaged in false patent marking under 35 U.S.C. § 292 because “Defendant has in the past marked, or caused to be marked, and presently marks, or causes to be marked at least the following products and/or the packaging thereof, with the ‘569 Patent: Heartgard Heartworm Canine Medication.” (See Docket #1 (“Complaint”) at ¶ 12.) Regarding the injury stemming from Merial’s supposed actions, Simonian merely declares that “each expired patent which is marked on a product contributes to causing harm to the Plaintiff, the United States and the general public.” (See, e.g., *id.* at ¶ 22.)

III. ARGUMENT

Simonian’s complaint (one of 39 false marking cases he has filed already in 2010) fails at every level. Most importantly, he has no standing under Article III to prosecute these claims, because he has not and cannot allege that he suffered any injury as a result of Merial’s alleged false marking. This lack of standing, by itself, compels dismissal of the complaint. In addition, Simonian’s complaint should be dismissed because he cannot meet the pleading requirements of Rule 9(b), and because he has no legally-cognizable claim against Merial.

A. Simonian Has No Standing Under Article III, And Thus This Court Lacks Subject Matter Jurisdiction To Adjudicate His Claims.

Simonian bears the burden “to allege facts demonstrating that he is a proper party to invoke judicial resolution of the dispute and the exercise of the court’s remedial powers.” *Warth v. Seldin*, 422 U.S. 490, 518 (1975). It is “the most basic doctrinal principle[]” that all plaintiffs—*qui tam* relators included—must have Article III standing. *Sprint Commc’ns Co., L.P. v. APCC Servs., Inc.*, 128 S. Ct. 2531, 2535 (2008). Without standing, there is no live case or controversy, and thus a court has no jurisdiction over the subject matter of the action; it must be dismissed. FED. R. CIV. P. 12(h)(3); see also, e.g., *Pollack v. U.S. Dept. of Justice*, 577 F.3d 736, 739, 743 (7th Cir. 2009), *cert denied*, No. 09-836, 2010 WL 128342 (Mar 22, 2010) (“Permitting a court to decide a case where the plaintiff does not have standing would ‘allow[] courts to

oversee legislative and executive action’ and thus ‘significantly alter the allocation of power ... away from a democratic form of government.’”); *Am. Fed’n of Gov’t Employees, Local 2119 v. Cohen*, 171 F.3d 460, 465 (7th Cir. 1999) (“Obviously, if a plaintiff cannot establish standing to sue, relief from this court is not possible, and dismissal under 12(b)(1) is the appropriate disposition.”).

To establish Article III standing, Simonian must show: (1) injury in fact, (2) causation, and (3) redressability. *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 771 (2000) (“These requirements together constitute the ‘irreducible constitutional minimum’ of standing, which is an ‘essential and unchanging part’ of Article III’s case-or-controversy requirement, and a key factor in dividing the power of government between the courts and the two political branches.”) (internal citations omitted). Simonian cannot get past the first prong.

1. Simonian Has Not Pled And Cannot Plead An Injury In Fact To Himself.

Injury in fact is the “hard floor of Article III jurisdiction that cannot be removed by statute.” *Summers v. Earth Island Inst.*, 129 S. Ct. 1142, 1151 (2009). This injury must be “concrete and actual or imminent,” not “conjectural or hypothetical.” *Id.* at 1149, 1151; *see also Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992); *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990); *Pollack*, 577 F.3d at 739. Simonian does not—and, indeed, cannot—allege any injury to himself. He is not a competitor of Merial and cannot allege that he was deceived or harmed in any way by Merial’s alleged false marking.

2. Simonian Has Not Pled And Cannot Plead Any Assignable Injury In Fact To The Public Or The Government.

Given that he cannot claim that he was personally injured, Simonian filed this action as a putative *qui tam* relator, seeking recovery for some vague injury to the general interest of the public and the Government in seeing that the laws are enforced. (Complaint at ¶ 22.) But

Simonian cannot avoid the core injury-in-fact requirement of Article III merely by donning the mantle of a *qui tam* plaintiff. *See Vt. Agency*, 529 U.S. at 771. *Qui tam* relators, who may suffer no “injury in fact” themselves, must nonetheless establish at a minimum that the public or the Government has suffered an injury in fact *and* that this injury is assignable to the relator, such that he or she can seek redress for it in litigation. *Id.* at 773-74. Absent an assignable injury in fact, there is no *qui tam* Article III standing. That is just the case with Simonian.

Legions of cases hold that a private party **cannot** establish Article III standing by relying on some injury to the abstract interest of the public or the Government in seeing that the laws are not violated. *Lance v. Coffman*, 549 U.S. 437, 442 (2007) (“The only injury plaintiffs allege is that the law ... has not been followed. This injury is precisely the kind of undifferentiated, generalized grievance...that we have refused to countenance in the past.”); *Fed. Election Comm’n v. Akins*, 524 U.S. 11, 24 (1998) (finding an “abstract” harm such as “injury to the interest in seeing that the law is obeyed ... deprives the case of the concrete specificity” necessary for standing); *Lujan*, 504 U.S. at 573-74 (“[H]arm to ... every citizen’s interest in proper application of the Constitution and laws ... does not state an Article III case or controversy.”); *Stauffer v. Brooks Bros., Inc.*, 615 F. Supp. 2d 248, 254 n.5 (S.D.N.Y. 2009) (“the Court doubts that the Government’s interest in seeing its laws enforced could alone be an assignable, concrete injury in fact sufficient to establish a *qui tam* plaintiff’s standing.”) (citation omitted); *see also* Myriam E. Gilles, *Representational Standing: U.S. ex rel. Stevens and the Future of Public Law Litigation*, 89 Cal. L. Rev. 315, 344 (2001) (“[C]laims seeking to vindicate the government’s non-proprietary, sovereign interests are not assignable.”).

The Supreme Court explained this principle when it addressed a “citizen-suit” provision of the Endangered Species Act, 16 U.S.C. § 1540(g) (“ESA”), which provided that “any person may commence a civil suit on his own behalf ... to enjoin any person ... who is alleged to be in

violation of any provision of this chapter.” *Lujan*, 504 U.S. at 571-72 (citation omitted). In holding that the plaintiff lacked Article III standing, the Court found Article III does not permit

[conversion of] the public interest in proper administration of the laws ... into an individual right by a statute that denominates it as such, and that permits all citizens ... to sue. If the concrete injury requirement has the separation-of-powers significance we have always said, the answer must be obvious: To permit Congress to convert the undifferentiated public interest in executive officers’ compliance with the law into an ‘individual right’ vindicable in the courts is to permit Congress to transfer from the President to the courts the Chief Executive’s most important constitutional duty, to ‘take Care that the Laws be faithfully executed,’ Art. II, § 3.

Id. at 576-77; *see also Allen v. Wright*, 468 U.S. 737, 761 (1984) (“The Constitution ... assigns to the Executive Branch, and not to the Judicial Branch, the duty to ‘take Care that the Laws be faithfully executed.’ U.S. Const., Art. II, § 3. We could not recognize respondents’ standing in this case without running afoul of that structural principle.”); *Valley Forge Christian Coll. v. Ams. United for Separation of Church and State*, 454 U.S. 464, 471-76 (1982) (explaining that Article III’s “case or controversy” requirement circumscribes Judicial Branch powers under separation of powers doctrine); *see generally* Tara Leigh Grove, *Standing as an Article II Nondelegation Doctrine*, 11 U. Pa. J. Const. L. 781 (2009) (explaining that Article III reinforces Article II nondelegation doctrine by prohibiting private prosecutorial discretion for violations of law, except for those private parties who can show a cognizable injury in fact).

This issue has also been addressed in the context of false patent marking litigation. Confronting the very same issue that is before this Court now, the district court in *Stauffer* ruled that a putative *qui tam* relator had no Article III standing to prosecute false marking claims against Brooks Brothers, alleging that the company marked certain of its bow ties with the numbers of expired patents. 615 F. Supp. 2d at 254. Like Simonian, the plaintiff in *Stauffer* offered only vague and generalized allegations of harm, *viz.*, that defendants’ conduct “ha[d] ‘wrongfully quelled competition with respect to [the marked products] thereby causing harm to

the economy of the United States” and that defendants “wrongfully and illegally advertis[ed] patent monopolies that they do not possess” and “ha[d] ‘benefitted [sic] in at least maintaining their considerable market share.’” *Id.* The court held that these conclusory statements were “insufficient to establish anything more than the sort of ‘conjectural or hypothetical’ harm that the Supreme Court instructs is insufficient.” *Id.* at 255 (internal citations omitted) (holding that the fact “[t]hat some competitor might somehow be injured at some point, or that some component of the United States economy might suffer some harm through defendants’ conduct, is purely speculative and plainly insufficient to support standing.”).²

Here, as in *Stauffer*, Simonian has failed “to allege with any specificity an actual injury to any individual competitor, to the market for [the products at issue], or to any aspect of the United States economy.” *Id.* Rather, Simonian has pled generalized allegations, virtually identical to the allegations made in *Stauffer*, that Merial’s conduct “is likely to, or at least has the potential to, discourage or deter persons and companies from commercializing competing products,” that Merial has allegedly “benefitted [sic] commercially and financially” and that “each expired patent which is marked on a product contributes to causing harm to the Plaintiff, the United States and the general public.” (Complaint at ¶¶ 19, 20, 22.) These generic and speculative allegations of injury in fact cannot establish standing.³

² The decision in *Pequignot v. Solo Cup*, 640 F. Supp. 2d 714 (E.D. Va. 2009) (“*Solo Cup*”), is not to the contrary. In *Solo Cup*, the defendant challenged the constitutionality of the statute itself, alleging that 35 U.S.C. § 292(b) lacks sufficient procedural safeguards and, on that ground, it violates *Article II*. *See id.* at 720-28. By this motion, Merial is not raising an *Article II* challenge to the statute. Rather, Merial points out that Simonian, like any plaintiff in any civil case, *Lujan*, 504 U.S. at 561, or any relator in any *qui tam* action, *Vt. Agency*, 529 U.S. at 771, must satisfy the injury in fact requirement of *Article III*. Simonian has failed to do so here.

³ Notwithstanding *Stauffer*, the Supreme Court authority, and the commentary discussed above, Merial is aware of another case in which the court, in a footnote and without analyzing or deciding the issue, assumed that a false marking claimant might have *Article III* standing based solely on an alleged violation of the law. *Solo Cup*, 640 F. Supp. 2d at 724 n.15. Merial respectfully submits that the *Solo Cup* footnote cannot save Simonian’s complaint. First, the *Solo Cup* footnote was dicta. The main thrusts of the *Solo Cup* decision were (1) whether 35 U.S.C. § 292(b) was a *qui tam* statute and (2) the constitutionality of 35 U.S.C. § 292(b) under *Article II*, not the relator’s lack of *Article III* standing. *See id.* at 720-28. Second, neither the *Solo Cup* footnote nor the *Solo Cup* decision is binding on this Court. Third, the *Solo Cup* footnote conflicts with the weight of applicable authority, as discussed above. Fourth, the *Solo Cup* footnote’s reasoning was flawed because it erroneously concluded that *Vt. Agency* did not distinguish sovereign injury from proprietary injury. *Id.* at 724 n.15. In fact, *Vt. Agency* *did* distinguish between the two by separately defining “the injury to its sovereignty arising from violation of its laws

Without any injury to himself, or any assignable injury to the government, Simonian has no Article III standing to prosecute his false marking claims against Merial. Accordingly, this Court lacks jurisdiction over the subject matter of Simonian's complaint, and the complaint should be dismissed, with prejudice, pursuant to FED. R. CIV. P. 12(b)(1).⁴ Alternatively, as set forth in the Motion to Stay filed contemporaneously by Merial, the Court may wish to defer resolution of this issue pending the Federal Circuit's decision in *Stauffer*, which is fully briefed and awaiting oral argument. The question of whether plaintiffs like Simonian have Article III standing to prosecute claims for false marking is squarely presented in that appeal, and the Federal Circuit's resolution of that threshold jurisdictional issue of first impression should guide this Court.

B. Simonian Fails To Plead His Claims With The Particularity Required By Rule 9(b).

Even if the Federal Circuit were to reverse the lower court in *Stauffer* and find that standing exists, it would not remedy Simonian's complaint, which is fatally defective for other, independent reasons—including the failure to plead his claims with the particularity required by FED. R. CIV. P. 9(b). The two elements of Simonian's false marking claim under Section 292 are (1) marking products with expired patent numbers and (2) intent to deceive the public. *Forest Group, Inc. v. Bon Tool Co.*, 590 F.3d 1295, 1300 (Fed. Cir. 2009). Because they require an

(continued...)

(which suffices to support a criminal lawsuit by the Government) and the proprietary injury resulting from the alleged fraud." 529 U.S. at 771. The Court held only that the *proprietary* injury could be assigned to a private party for Article III standing purposes. *See id.* at 766, 773 (holding that False Claims Act "effect[ed] a partial assignment of the Government's *damages claim*") (emphasis added). The Court did *not* hold that sovereign injury, *i.e.*, the source of the government's ability to enforce its criminal laws, could be assigned to a private party for Article III standing purposes. The *Solo Cup* case is on appeal to the Court of Appeals for the Federal Circuit.

⁴ On March 17, 2010, Judge Armstrong in the Northern District of California held that a *qui tam* relator has standing to assert the government's sovereign interest in a false marking case. *Juniper Networks v. Shipley*, No. C 09-0696 SBA, 2010 WL 986809 (N.D. Cal. Mar. 17, 2010). *See* Exhibit A. Merial submits that this decision is also based on a misreading of *Vt. Agency*, which did not hold that the government can assign its *sovereign* interest to a private party. Such a holding would be contrary to *Lujan* and other Supreme Court precedent establishing that an interest in seeing the laws obeyed is not sufficient to confer standing on a private party. Rather, *Vt. Agency* dealt with assignment of an injury to the government's *pecuniary* interest under the False Claims Act. 529 U.S. at 773.

“intent to deceive,” claims arising under the false patent marking statute constitute fraud-based claims and are thus subject to the heightened pleading requirements of Rule 9(b). *Juniper Networks v. Shipley*, No. C09-0696 SBA, 2009 WL 1381873, at *4 (N.D. Cal. May 14, 2009) (Exhibit B).

The particularity required by Rule 9(b) demands that plaintiffs “plead the circumstances constituting fraud in detail –the ‘who, what, when, where, and how...’” *Arazie v. Mullane*, 2 F.3d 1456, 1465 (7th Cir. 1993) (citing *DiLeo v. Ernst & Young*, 901 F.2d 624, 626 (7th Cir. 1990)). Under this heightened pleading requirement, plaintiffs “‘must do more pre-complaint investigation to assure that the claim is responsible and supported, rather than defamatory and extortionate.’” *Borsellino v. Goldman Sachs Group, Inc.*, 477 F.3d 502, 507 (7th Cir. 2007) (citation omitted). The pleadings must “contain explicit rather than implied expression of the circumstances constituting fraud.” *Exergen v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009) (holding that Rule 9(b) requires that “pleadings allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind”). Simonian did not come close to this mark, however, perhaps because of his admitted desire to race to the courthouse with this and all of his other recently-lodged false marking actions. *See* Exhibit C (Simonian’s counsel instructing colleagues not to “worry about making the complaints [against Merial and others] too elaborate. We just need to get on file.”).⁵

The alleged “fraud” here is Merial’s marking an expired patent number on the packages of HEARTGARD “*for the purpose of deceiving the public.*” 35 U.S.C. § 292 (emphasis added). As to this key element of intent to deceive, however, Simonian does not offer a single supporting

⁵ Not surprisingly, in his haste to “get on file” a large number of false marking complaints against a host of different companies, Simonian made a number of factual mistakes in his complaint against Merial. For example, Simonian claims that the ‘569 Patent expired on July 31, 1998 (Complaint at ¶ 2), when, in fact, it expired on April 16, 2001. *See* discussion *infra*, pp. 13-14. Simonian also claims that Merial “has many decades of experience applying for, obtaining and litigating patents,” (Complaint at ¶ 15), when Merial was not even founded until 1997. (Exhibit D.)

fact. Instead, his complaint sets forth only a series of rhetorical conclusions, virtually all of which are pled on information and belief. For example, he alleges that Merial:

- has in the past or currently is responsible for marking the products and or packaging of HEARTGARD with the ‘569 Patent (Complaint at ¶ 12);
- knows, or should know (by itself or by its representatives), that the ‘569 Patent marked on HEARTGARD has expired (*id.* at ¶ 17);
- knows, or should know (by itself or by its representatives), that HEARTGARD is not covered by the expired ‘569 Patent marked on such product because an expired patent has no prospective rights (*id.* at ¶¶ 14, 17);
- intentionally included the expired ‘569 Patent in the patent markings of HEARTGARD, in an attempt to deter competitors from commercializing competing products (*id.* at ¶¶ 18, 19);
- marks HEARTGARD with the expired ‘569 Patent for the purpose of deceiving the public into believing that something contained in or embodied in the product is covered by or protected by the expired ‘569 Patent (*id.* at ¶ 18); and
- knows, or reasonably should know, that marking HEARTGARD with false patent statements was and is illegal under Title 35 United States Code, and at a minimum, had and has no reasonable basis to believe that its use of the false markings was or is proper or otherwise permitted under federal law (*id.* at ¶ 21).

Critically absent from Simonian’s complaint are any facts that would support an inference of bad intent. Merely asserting fraud on “information and belief” is not enough; the Seventh Circuit has instructed that such allegations “are insufficient, even if the facts are inaccessible to the plaintiff, unless the plaintiff states the grounds for his suspicions,” which Simonian has not done here. *Uni*Quality, Inc. v. Infotronx, Inc.*, 974 F.2d 918, 924 (7th Cir. 1992). This standard applies equally to *qui tam* relators. *United States ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 378 (7th Cir. 2003) (holding *qui tam* relators must do more than merely allege fraudulent schemes and then conclusively assert that fraud occurred).

Ultimately, Simonian falls far short of identifying “the who, what, when, where, and how” that is required by Rule 9(b). The few “facts” that he sprinkles into the complaint to support his “intent to deceive” conclusion (that Merial is a “sophisticated” company, has

“experience” with patents, and allegedly should have known that the ‘569 Patent was expired)⁶ do not support, or even suggest, an intent to deceive the public or Merial’s competitors. Indeed, in a recent decision, the United States District Court for the District of Delaware dismissed similarly threadbare pleadings of intent as insufficient to meet even the default pleading standards of Fed. R. Civ. P. 8(a) (“Rule 8(a)”) and *Twombly*. See *Brinkmeier v. Graco Children’s Prods. Inc.*, No. 09-262-JJF, 2010 WL 545896, at *4-5 (D. Del. Feb. 16, 2010) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)) (Exhibit E).

Like Simonian, the *Brinkmeier* relator tried to parlay the fact that expired patent numbers appeared on defendant’s products into an inference of deceptive intent. See *id.* at *4. In particular, the *Brinkmeier* relator alleged that: (1) defendant had an Intellectual Property Manager responsible for patent markings; (2) because certain patents had expired, defendant “cannot have any reasonable belief that such products are protected by such patents;” (3) defendant “‘knows, or should know’ that products have been falsely marked;” and (4) “[u]pon information and belief, [defendant] marked products ... with expired patent for the purpose of deceiving the public into believing that something contained in or embodied in the products is covered by or protected by the expired patent[s].” *Id.* The *Brinkmeier* court rejected these allegations even under the lesser Rule 8(a) standards: “These allegations alone do not supply enough factual matter to suggest an intent to deceive, and amount to nothing more than the ‘mere labels and conclusions’ prohibited by *Twombly*.” *Id.*⁷ Because Simonian’s pleadings are similarly, if not more, conclusory, the same result should apply here, and Simonian’s complaint should be dismissed.

⁶ See Complaint at ¶¶ 15-16.

⁷ In *Brinkmeier*, the court also found that the relator pled sufficient facts as to *one* act of patent marking where she alleged that: (1) defendant had been sued by two competitors for infringing the marked patent; and (2) defendant revised its patent markings at least three times since the marked patent expired in June 2007. *Id.* at *4. Simonian’s pleadings come nowhere close to that level of detail.

C. Simonian Has No Legally Cognizable Claim Against Merial.

There is a practical reason why Simonian does not plead any claims against Merial with the particularity required by Rule 9(b): he has no such claims to plead.

Simonian's claims fail as a matter of law because they rest on a fundamental, and faulty, assumption—namely that Merial could have intended to deceive potential competitors into believing that HEARTGARD is currently covered by a patent (and thus causing them to defer the introduction of any competing products) merely by adding an expired patent number to the package. (Complaint at ¶ 18.) In the pharmaceutical field, that argument is a non-starter.

Setting aside for the moment the indisputable fact that Merial's competitors are sophisticated companies that understand patents and would never be deterred from pursuing a competitive product by a patent number printed on a package,⁸ the bigger issue for Simonian is that, because of Food and Drug Administration ("FDA") regulations, any company interested in launching a competing heartworm medication (or any animal drug relying on the '569 patent) would know without question that no patents currently cover the accused Merial products. For each of their marketed drug products, companies like Merial are required to include in FDA's publicly-available list of "FDA Approved Animal Drug Products," (known as the "Green Book") those patents that they believe cover the products.⁹ 21 U.S.C. § 360b(b)(1) ("The applicant shall file with the application the patent number and the expiration date of any patent which claims the new animal drug for which the applicant filed the application"). Any company that subsequently applies for FDA approval to market a generic version of one of those marketed drugs must

⁸ And, it goes without saying that members of the general public are not in a position to develop and market pharmaceutical products.

⁹ The Court may consider evidence outside of the pleadings on a motion under Fed. R. Civ. P. 12 ("Rule 12") without converting it into a motion for summary judgment when such evidence is a matter of public record. *Henson v. CSC Credit Servs.*, 29 F.3d 280, 284 (7th Cir. 1994) (holding that the district court properly relied on public court documents in deciding defendants' Rule 12(b)(6) motion to dismiss). Publications from administrative agencies, such as the United States Patent and Trademark Office and the FDA are public records of which the court may properly take judicial notice. *Menominee Indian Tribe of Wis. v. Thompson*, 161 F.3d 449, 456 (7th Cir. 1998) (In deciding a Rule 12 motion, "[j]udicial notice of historical documents, documents contained in the public record, and reports of administrative bodies is proper.").

consult the Green Book and include in its abbreviated new animal drug application (“ANADA”) a certification regarding any listed patent on which it is basing its ANADA (indicating whether the patent is still in effect or expired). *See, e.g.*, 21 U.S.C. § 360b(n)(1)(H).

In Merial’s case, the Green Book explicitly disclosed the expiration date of the ‘569 Patent when the patent issued, and it tracked all changes in the patent’s expiration date as the law changed and as patent owner Merck sought various patent term extensions for the patent.

When it issued in 1980, the ‘569 Patent was set to expire on April 22, 1997, and this expiration date was published in the Green Book. *See FDA Approved Animal Drug Products (“Green Book”) § 3*, at 3.5-3.7 (1995) (relevant pages attached as Exhibit F). On December 8, 1994, however, the law changed and then-existing patents were given a term of either 17 years from issuance or 20 years from the filing date of the earliest patent application in the chain, whichever was longer. 35 U.S.C. § 154(c)(1). In the case of the ‘569 Patent, the expiration date changed to October 3, 1997, which was also published in the Green Book. *See Green Book § 3*, at 3.4-3.7 (1996) (relevant pages attached as Exhibit G).

The law gives patentees an opportunity to seek an extension of the patent term to compensate for delays before the FDA. 35 U.S.C. § 156. Merck applied for and received an extension of the ‘569 patent term. Merck was first granted a one-year interim extension for certain products, moving the expiration date to October 3, 1998 for those products. *See Green Book § 3*, at 3.5-3.8 (1997) (relevant pages attached as Exhibit H). A second interim extension was granted for certain products, moving the expiration date to October 3, 1999. *See Green Book §§ 3, 8*, at 3.3-3.8, 8.53 (Jan. 15, 1998) (relevant pages attached as Exhibit I). Ultimately, the PTO granted a term extension of 1,291 days for specific products, moving the expiration date to April 16, 2001 for those products. *See Exhibit J*. The changes to the expiration date of the ‘569 Patent were reported in the Green Book, along with a statement that for other products not

mentioned, the '569 expiration date remained at October 3, 1997. *See Green Book*, at Green Book Supplement Page (1997) ("Claims approved before 11/22/96 remain subject to the current expiration date of 10/03/97.") (Exhibit H); *Green Book* § 8, at 8.53 (1998) ("Claims approved before 11/22/96 remain subject to the expiration date of 10/03/97.") (Exhibit I).

Today, one can still easily determine the expiration date of the '569 Patent by searching the patent extension terms on the PTO's website. *See* USPTO.gov, Patent Terms Extended Under 35 § U.S.C. 156, <http://www.uspto.gov/patents/resources/terms/156.jsp> (showing expiration date of the '569 Patent) (last visited Apr. 9, 2010) (Exhibit K).

Not only was the expiration information for the '569 Patent published and regularly updated in the publicly-available Green Book—a source routinely consulted by competitors in the animal health industry, and, indeed, a source that competitors are ***required by law*** to consult if they want to manufacture a competing product—this same information was readily available from the PTO and published in the PTO's Official Gazette. *See* Exhibits L-N. The information about the '569 Patent's term extensions is also publicly available directly from the PTO, as all file histories are public records and many, including the file history for the '569 Patent, are retrievable in an instant on-line. *See* USPTO.gov, <http://portal.uspto.gov/external/portal/pair> (last visited April, 28, 2010).

Finally, one could have referred to the Green Book versions in years after the October 3, 1997 '569 Patent expiration date that applied to HEARTGARD, and noted that HEARTGARD and the '569 Patent were no longer listed in the Patent Information section, indicating that the '569 patent had expired as to HEARTGARD. *See* 1998, 1999, 2000 and 2001 *Green Book* (relevant pages attached as Exhibits I, O-Q).

At all times, the expiration date of the '569 Patent was and is readily available to anyone and, most importantly, any competitor interested in launching a competing heartworm medicine

is required, by law, to review the Green Book and analyze whether any extant patents actually covered those products. Not only could competitors readily ascertain the patent expiration date, as noted above, but once the '569 Patent expired in 1997 as to HEARTGARD, generic competitors actually did launch competitive products. *See Green Book* § 7, at 7.6-7.17 (2009) (showing the application and approval history of generic ivermectin products that compete with HEARTGARD, beginning in 1998) (relevant pages attached as Exhibit R).

Given these facts, there is no way Merial could ever intend to deceive a competitor about patent coverage merely by listing patent numbers on the product or its packaging. Accordingly, because intent to deceive is an essential element of a false patent marking claim, Simonian's complaint does not state a claim for which relief can be granted, and it should be dismissed.

IV. CONCLUSION

For these reasons, the Court should dismiss the complaint with prejudice because Simonian has not and cannot allege a cognizable injury in fact to support Article III standing, he has not and cannot satisfy the pleading requirements of Rule 9(b), and he has no legally cognizable claim against Merial for false marking.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing Memorandum In Support Of Defendants' Motion To Dismiss, With Prejudice was filed via CM/ECF on April 30, 2010, and was served upon the parties listed below via CM/ECF:

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